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Real world evidence—
Data asset management
Trends in evidence management

Overview

Life Sciences organizations, health care providers and health care payers – all key stakeholders in the health care system are feeling the impact of the disruption caused by macro and legislative pressures. The trajectory of health spend is unsustainable (e.g. health care spend is $2.6T and growing unsustainably) and the Accountable Care Act seeks to increase the access to and management of data in efforts to transition health care from a volume to value-based care model. The result is that stakeholders will need to prioritize the management of data in efforts to better understand which drugs and therapies (1) deliver high value and (2) provide the best health outcomes.

Life sciences organizations, as the developer and manufacturer of these drugs, are particularly interested in better understanding the value of drugs and drug therapies across the health care ecosystem. Real World Evidence (RWE) has emerged as a powerful and broad-based capability to shape and inform the shift to value-based, personalized health care in the management and monitoring of data. What began as a concept for outcomes research has matured into an ever expanding framework of data and analytic capabilities to enable more accurate and more efficient health care and health product decision making.

Therefore, RWE is now perceived as a set of capabilities to help address complex health care questions regarding value and effectiveness of drugs in the marketplace. The scope of RWE for life sciences organizations extends from early R&D through commercialization and beyond Phase IV studies. The data in scope for RWE and Real World Data (RWD) is vast and can span from genomic data (GWAS), clinical trials data, medical claims data and patient data from EHR/EMRs.

Figure 1 describes the path of RWD within an organization:

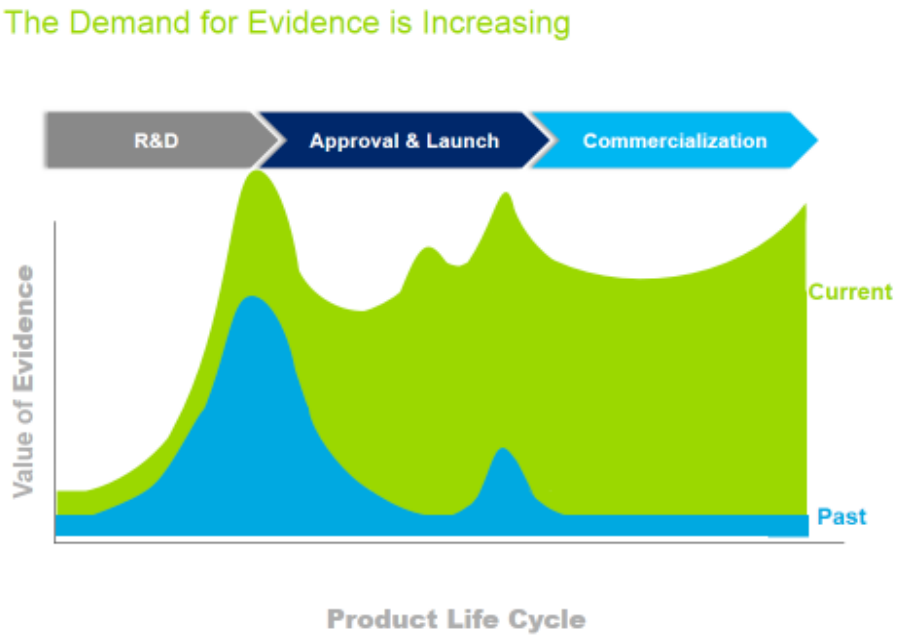


Figure 1-Real World Data (RWD) Mandate

CBO[1]

Gathering RWD is the base-building block of all RWE activities, and RWD sources provide unique insights if calibrated correctly and optimized for the evidence strategy of each enterprise.

To do so organizations need to create tools or activities around the aggregation, exchange, and/or analysis of RWD; and build value-added applications of RWD to various health care stakeholders. Central to any RWE activity is the need to assess, track, approve, use and manage RWD assets within an organization. The evidence value behind each one of these RWD sources is different during the product lifecycle. Understanding which data assets to utilize for a specific RWE study in order to drive the right hypothesis is a complex, time-consuming and laborious process that can be streamlined and standardized via a RWE solution that integrates the most effective tools from across the enterprise ecosystem. RWD sources enable researchers to derive greater value across key processes that define the study outcomes. As the mandate to demonstrate value through precision medicine parameters like efficacy, safety, effectiveness and accuracy grows, the need to acquire, understand and govern new data sources increase.

In the process of identifying, acquiring, provisioning and monitoring RWD assets, organizational processes to govern the management of RWD assets today are often inefficient from a business strategy as well from a solution side. Often times, the same exact RWD asset is licensed multiple times within the same organization by multiple business units because of the fragmented nature of how budgets and operating plans are realized in the industry. The level of collaboration support needed to manage vendors as a single entity (as opposed to multiple threads) across business units generally does not exist either. And most importantly, the asset investment justification that touches on key effectiveness metrics such as commercial efficiency, adoption and evidence value being generated.

Examples and sources of RWD are depicted in Figures 2 and 3 below:

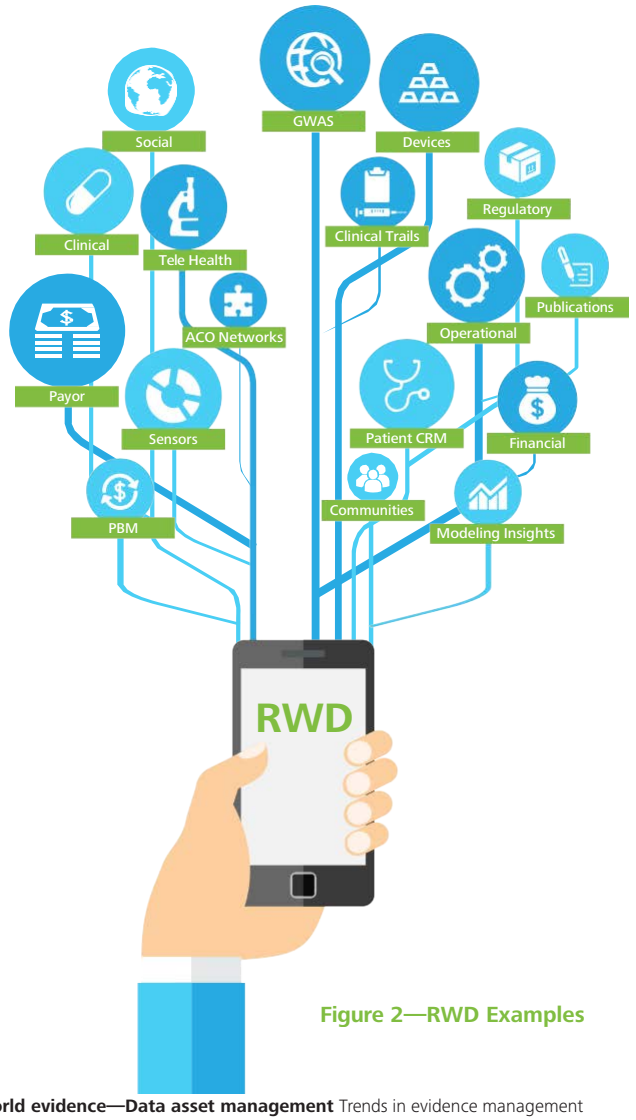


Figure 2—RWD Examples

Overview

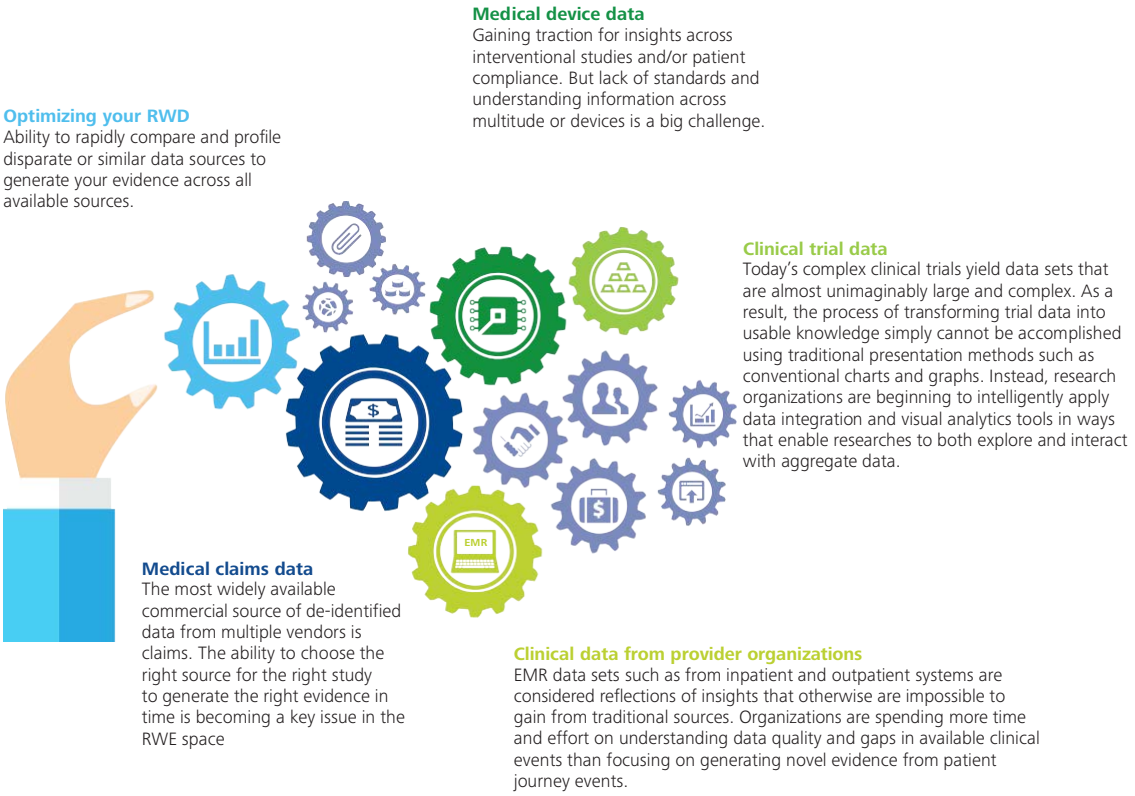


Figure 3—RWD Examples

Implementation of a Data Asset Explorer (DAE) is designed to address these challenges with both a strategy and a systems approach that touches on RWD governance, licensing compliance and risk management, utilization, investment management, profiling and optimization. All of which are needs identified within organizations that are deploying an RWE strategy across the product lifecycle. DAE includes capabilities to help organizations understand what types of RWD exists, the best way to access these RWD assets, and how to optimize analysis (including access to its stakeholder groups) and demonstrate value behind these assets. Currently, a majority of the activities on RWD focus on capturing and digitizing health information (e.g. a large health care system allows patient to submit health information online to physicians and their EMRs via medical devices.). While the scope for RWD is vast and complex, managing RWD assets via DAE is important so that life sciences organizations can answer the following questions:

- What are the RWD assets that they own?
- What are specific characteristics for this RWD asset (e.g., EHR, Diabetes, etc.)? And how best can we enable a search for/ within the scientific community across the list of these RWD assets?
- How long do they have access to this RWD asset?
- What are the rules governing the usage to the RWD asset? (e.g. data residency rules)
- How do they access this RWD asset?
- Which RWE study has used a specific RWD asset?
- How do they demonstrate the value behind these data assets to justify continued investment in licensing and support costs?
- How does the organization stay in compliance with the asset licensing policies?
- How do we govern utilization and investment across these data assets

The following high-level requirements drive DAE platform solution development to enable population and growth of a list of RWD assets:

Primary	Advanced
• Accounting for breadth of RWD sources since information can be gathered across the health care continuum from a variety of sources • Managing different stakeholders (data stewards, procurement, legal, etc.) in identification, approval and procurement • Supporting collaboration across the different stakeholders • Listing and managing the list of identified-through-approved RWD assets • Providing an intuitive and simple mechanism to search the DAM for RWD assets	• Profiling RWD assets and store key metadata about the RWD asset • Providing the RWE community with recommendations on best RWD asset to leverage for a RWE study • Supporting complex workflow and approval processes to help in getting a RWD asset ready for internal use • Tracking and monitoring RWD asset license usage • Comparing across a group of RWD assets to review set of values across common fields • Tracking utilization of RWD asset across RWE studies • Linking to actual dataset within a RWD asset

Solution Characteristics for a Data Asset Manager (DAM)

Capturing & Profiling 	• Data model to capture information about a specific RWD asset (e.g., RWD Name, Therapeutic Area, Owner Function, Data Steward Name, etc.) • Profiling the RWD asset and store key metadata about the RWD asset
Collaboration & Workflow 	• Managing different stakeholders (data stewards, procurement, legal, etc.) in identification, approval and procurement • Managing licensing compliance and policy driven regulatory processes to govern data assets utilization across the enterprise • Supporting collaboration across the different stakeholders within an organization to understand, discuss, share and explore commercial efficiency and evidence value across different data assets before requesting access • Managing compliance and regulatory guidelines for RWD usage and its procurement • Enabling complex workflow and approval processes to help in provisioning and fulfillment of a RWD asset ready for internal use
Guidance & Insights 	• Providing the RWE community with recommendations on what best RWD is available to be used in a study • Tracking and monitoring RWD asset license usage • Comparing across a group of RWD assets to review sets of values across common fields • Tracking utilization of RWD asset across RWE studies • Linking to actual dataset within a RWD asset
Exploration 	• Accounting for breadth of RWD sources since information can be gathered across the healthcare continuum from a variety of sources • Listing and managing the list of identified through approved RWD assets • Providing an intuitive and simple mechanism to search the DAE for RWD assets

Approaches for Data Asset Management

While there is no one single approach, we see that many point solutions exist today to enable DAM needs that range from specialized service offerings to Software as a Service (SaaS) solutions. Across the myriad of these solutions, there are a set of key factors:

- an **environment to adapt and continuously capture and manage RWD assets**
- **strong knowledge management and domain expertise for capturing and maintaining the RWD asset inventory** in DAE
- a **defined cataloging process to maintain RWD asset list** based on set of processes enabled by workflows and approvals
- an **operating model that includes governance** across cross functional groups—business, financial and legal in order to maintain the inventory of RWD data assets

Centralized Document/List

- Simple list maintained using Excel or Word Document.
- Stored on a fileshare and made accessible to a subset secure group.
- Extending collaboration solution to develop DAE
- Limited data model
- Provides rich collaboration and workflow

Collaboration Solution

- Extending collaboration solution to develop DAE
- Limited data model
- Provides rich collaboration and workflow

Figure 4 — DAM Implementation Approaches

Custom Web Application

- Custom web solution to maintain list
- Includes a basic data model
- Limited reporting and collaboration

Platform Solution

- Developed on application platform
- Flexible data model
- Provides rich collaboration and workflow

Of the four implementation approaches for a DAE outlined in Figure 4, the Platform Solution provides the most optimal path for results/ to achieve the desired objectives/outcomes given the intrinsic capabilities provided by a Platform (Application Platform as a PaaS, e.g.: Salesforce, Oracle):

- Speed
- Modular architecture that is easily extensible
- Security
- Scalability
- Collaboration features
- Data and content storage
- Standard APIs such as REST/SOAP based web services to support integration across solutions
- Built-in rich set of reporting capabilities to surface information

While a Platform Solution may be most effective approach to managing data assets, all of these implementation approaches enable:

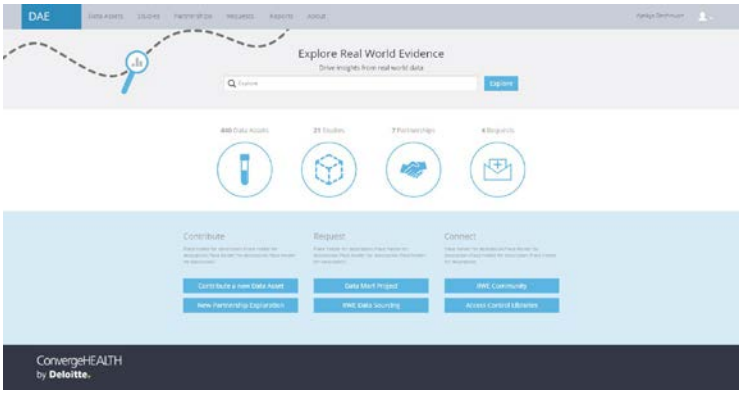
- Rapid deployment based on ability to develop, package and instantly deploy applications
- Faster application development based on access to rich APIs, application frameworks, and Visual tools to support application development
- Increased agility based on faster time to market, quicker application delivery with fewer resources
- Reduced cost resulting in improvements of TCO and ROI for building applications on platforms compared to traditional application development efforts

DAM Solution from Deloitte and ConvergeHEALTH by Deloitte: Data Asset Explorer (DAE)

DAE is a hosted secure web-based application enabled for life sciences organizations as a Software as a Service (SaaS) solution. It allows RWE users to access and manage their RWD assets while maintaining a RWD inventory. Listed below are the set of capabilities enabled by DAE:

- Capturing RWD asset metadata details based on data model that includes Industry leading practices and dictionary/vocabularies. This includes maintaining the listing of all RWD assets including the status identified-through-approved.
- Ability to visualize and manage relationships between different RWE modalities products, studies, trials, data assets and utilization across the RWE.
- Ability to drive policy-driven governance and approval processes for different stakeholders (data stewards, procurement, legal) as part of a lifecycle RWD asset—identification, approval and licensing procurement.
- Collaboration between RWE users to allow discussions across studies, data assets, products and experience dealing with generating evidence.
- Intuitive custom metadata-based federated search across data assets.
- Ability to rapidly profile RWD asset with novel data profiling solutions and store profile data about the RWD asset.
- Ability to link advanced guided analytic solutions to approved data assets for rapid analysis across various functions.
- Ability to provide end-to-end evidence audit profile demonstrating data assets profiled across different sources to analytics performed across assets to generate final hypothesis.
- Recommending best RWD asset to leverage for a RWE study.
- Supporting complex workflows that manage approval processes to help in getting a RWD asset ready for internal use.
- Tracking and monitoring RWD utilization reports across various RWE modalities.
- Comparing across a group of RWD assets to review set of values across common fields.

Fig. 5: DAE from ConvergeHEALTH by Deloitte: A Deloitte solution to organize life sciences organizations around data assets



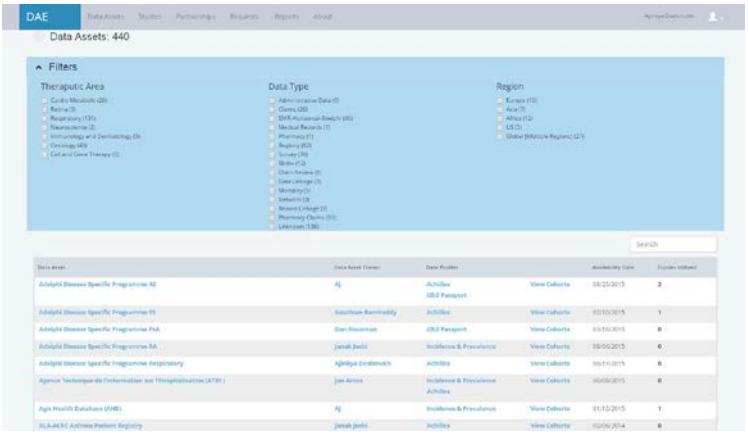


Fig. 6: Visual of how DAE can organize data assets

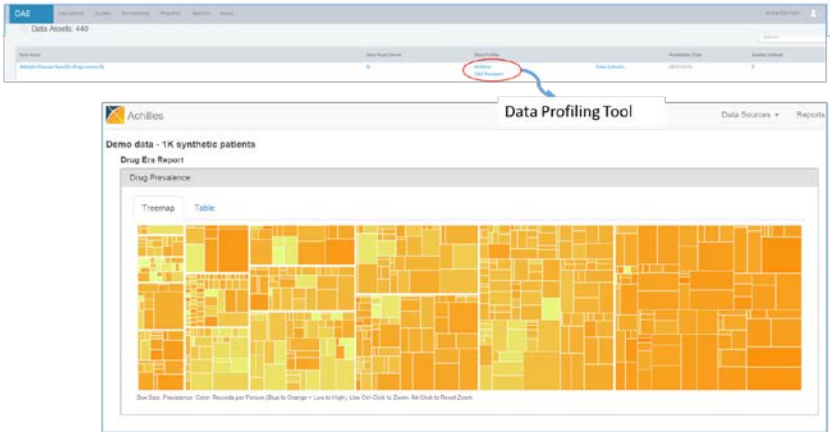
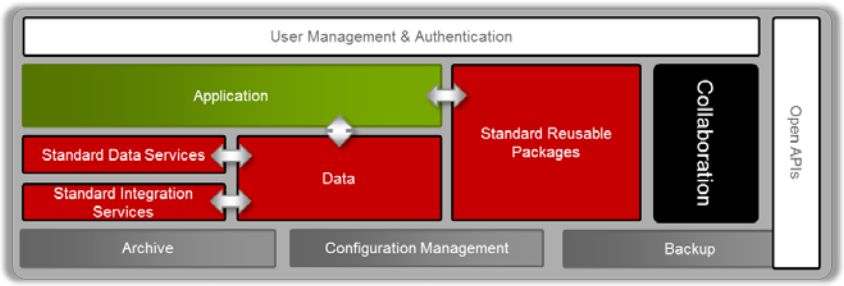


Figure 7: DAE link to external data profiling tool

Below is a high level DAE solution architecture:

Figure 7—DAE solution architecture



- Security layer that manages access to application via user management and authentication layer
- Custom user interface screens built using HTML5.0
- Enhanced search based on faceted search based on business controlled metadata values
- Managing large search result sets using pagination to minimize user clicks
- Search UI page enables faster drill down of records through custom filters as options that inject conditions into the search query.

Conclusion

Real World Data (RWD) plays an integral role in RWE activities within an enterprise. Managing an organizations' RWD assets requires a Data Asset Management (DAE) solution. DAE has been implemented in a number of ways. This paper outlines a set of DAE capabilities that need to be enabled and factors for implementing a DAE which is a Deloitte DAE solution. Deloitte's DAE solution is available as a SaaS solution as well as can be deployed on-premise. Deloitte's experienced team can help define the governance process, the data model for DAE and configure to include integration to external source systems and characterization tools.

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